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09/889,751	07/20/2001	Paul Kenneth Rand	PG3604USW	8846

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DAVID J LEVY, CORPORATE INTELLECTUAL PROPERTY
GLAXOSMITHKLINE
FIVE MOORE DR., PO BOX 13398
RESEARCH TRIANGLE PARK, NC 27709-3398

EXAMINER

PATEL, MITAL B

ART UNIT	PAPER NUMBER
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3743

DATE MAILED: 05/19/2004 *6*

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/889,751

Applicant(s)

RAND, PAUL KENNETH

Examiner

Mital B. Patel

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 February 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-43 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 3-43 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Response to Amendment/Arguments

1. Applicant's arguments filed 2/20/04 have been fully considered but they are not persuasive.
2. In response to Applicant's arguments with respect to a "substantially planar face," the Examiner would like to point out that at least a portion of the side of the coiled strip forms a **substantially** planar face.
3. In response to Applicant's arguments with respect to the carrier being "substantially rigid," the Examiner considers the carrier in its coiled or spiral state to be substantially rigid since it maintains that coiled/spiral shape prior to being unwound.
4. In response to Applicant's arguments with respect to the carrier storable in a flat spiral configuration, when viewing the carrier from the top, it is storable in a flat spiral configuration, i.e. the top surface of the carrier is flat yet still in a spiral configuration when stored into the cartridge.
5. In response to Applicant's arguments that the medicament carrier is not a disk, it should be noted that a disk is defined as a circular object in which case the carrier of Davies is a circular object when stored.
6. In response to Applicant's arguments with respect to helical extension, the Examiner maintains that Davies teaches helical extension is as much as Applicant teaches helical extension.

7. In response to Applicant's arguments that Everett does not teach a piercer, it should be noted that a piercer

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1, 3-8, 10-22, 26-39 and 41-43 rejected under 35 U.S.C. 102(b) as being anticipated by Davies et al (GB 2242134).
10. **As to claim 1**, Davies teaches a medicament cartridge for use in an inhalation device comprising a carrier **401** having a substantially planar first face (**the Examiner considers the carrier to be substantially planar and having a first face when viewing the carrier from the side**) and a plurality of medicament retainers **402** in a single spiral path arrangement along said first face (**See Figs. 13-16**). **Please note that Davies teaches a single spiral path as much as Applicant teaches a single spiral path given that applicant has not defined in the specification what a single spiral path constitutes.**
11. **As to claim 3**, Davies teaches a medicament cartridge wherein the carrier is substantially rigid (**See Figs. 13-16**).
12. **As to claim 4**, Davies teaches a medicament cartridge wherein the carrier is circular in shape and is rotationally mountable (**See Figs. 13-16**).

13. **As to claim 5**, Davies teaches a medicament cartridge wherein each medicament retainer comprises a pocket **402** (**See Page 17**).
14. **As to claim 6**, Davies teaches a medicament cartridge wherein a seal is provided to each pocket (**See Page 17**).
15. **As to claim 7**, Davies teaches a medicament cartridge wherein the seal comprises a sealing tape **404** arranged along the spiral path and wherein each pocket is accessible by progressive removal of the tape from the spiral path.
16. **As to claim 8**, Davies teaches a medicament cartridge wherein each medicament carrier comprises a hole **402** in the carrier.
17. **As to claim 10**, Davies teaches a medicament cartridge wherein the carrier is elongate, storable in a flat spiral configuration and extendable as a helix (**See Fig. 16**).
18. **As to claim 11**, Davies teaches a medicament cartridge wherein the medicament retainers are serially arranged along the elongate carrier (**See Fig. 16**).
19. **As to claim 12**, Davies teaches a medicament cartridge wherein each medicament retainer comprises a cavity **402** in the elongate carrier.
20. **As to claim 13**, Davies teaches a medicament cartridge wherein a seal is provided to each cavity.
21. **As to claim 14**, Davies teaches a medicament cartridge wherein the seal comprises a sealing tape **404** and each cavity is individually accessible by peelable removal of the sealing tape.
22. **As to claim 15**, Davies teaches a medicament cartridge wherein each medicament retainer is sized to retain a single dose of medicament (**See Page 5**).

23. **As to claim 16**, Davies teaches a medicament cartridge having from 60 to 500, preferably from 100 to 300, medicament retainers (**See Page 6**).

24. **As to claim 17**, Davies teaches a medicament cartridge wherein the medicament dose is applied to the carrier by wet or dry printing methods. It should be noted that the claim is directed to a device/apparatus and as such patentable weight is given to the end product and not the process. "Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted).

25. **As to claim 18**, Davies teaches a medicament cartridge wherein the medicament is present in one or more of the medicament retainers (**See Fig. 16**).

26. **As to claim 19**, Davies teaches a medicament cartridge for use in an inhalation device comprising an elongate carrier having a substantially planar first face (**the Examiner considers the carrier to be substantially planar and having a first face when viewing the carrier from the side**) having plurality of medicament doses thereon, wherein the doses are in a single spiral path arrangement along the first face (**See Fig. 16**). **Please note that Davies teaches a single spiral path as much as Applicant teaches a single spiral path given that applicant has not defined in the specification what a single spiral path constitutes.**

27. **As to claim 20**, Davies teaches a medicament cartridge wherein the elongate carrier is storable in a flat spiral configuration and extendable as a helix (**See Fig. 16**).

28. **As to claim 21**, Davies teaches an inhalation device comprising a housing **410** having an air inlet **140,121**, an air outlet **420** and an airway therebetween; a medicament carrier **401** having a plurality of medicament retainers in a single spiral path arrangement on a planar face of the carrier; and a mover **416,470,471** for moving the medicament carrier relative to the housing so as to bring successive medicament retainers individually into communication with the airway. **Please note that Davies teaches a single spiral path as much as Applicant teaches a single spiral path given that applicant has not defined in the specification what a single spiral path constitutes.**

29. **As to claim 22**, Davies teaches an inhalation device wherein the medicament carrier is a substantially rigid circular disk which is rotatable relative to the housing (**See Fig. 16**).

30. **As to claim 24**, Davies teaches an inhalation device wherein each medicament retainer comprises a pocket in a first face of the disk.

31. **As to claim 26**, Davies teaches an inhalation device comprising a housing **410** having an air inlet **140,121**, an air outlet **420** and an airway therebetween; a substantially planar medicament carrier **401** having a plurality of medicament retainers **402** in a single spiral path arrangement in the plane of the medicament carrier, each medicament retainer having a seal **404**; an actuator **416,470,471** for progressively unsealing each medicament retainer on the spiral path. **Please note that Davies**

teaches a single spiral path as much as Applicant teaches a single spiral path given that applicant has not defined in the specification what a single spiral path constitutes.

32. **As to claim 27**, Davies teaches an inhalation device additionally comprising a mover **472,473,475** for moving the medicament carrier relative to the housing so as to bring successive medicament retainers individually into communication with the airway.

33. **As to claim 28**, Davies teaches an inhalation device wherein each medicament retainer comprises a pocket **402**.

34. **As to claim 29**, Davies teaches an inhalation device wherein the seal comprises a sealing tape **404** arranged along the spiral path and wherein each pocket is serially accessible by peelable removal of the tape.

35. **As to claim 30**, Davies teaches an inhalation device wherein an end of the sealing tape connects to the actuator and peelable removable of the sealing tape is achievable by movement of the actuator (**See Pages 18-19**).

36. **As to claim 31**, Davies teaches an inhalation device wherein the actuator is rotatable relative to the housing such that rotation of the actuator results in coiling of the tape around the actuator (**See Pages 18-19**).

37. **As to claim 32**, Davies teaches an inhalation device wherein the actuator is an axially mounted tapered pole (**See Pages 18-19; See Figure 16 which shows actuator 470 to be tapered from bottom to top**).

38. **As to claim 33**, Davies teaches an inhalation device comprising a housing **410** having an air inlet **140,121**, an air outlet **420** and an airway therebetween; an elongate

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carrier **401** having a plurality of medicament retainers **402**, wherein the elongate carrier is storable in a flat spiral configuration within a plane forming a substantially planar face; and a mover in communication with the elongate carrier for helically extending the elongate carrier such as to successively move each medicament retainer to access position.

39. **As to claim 34**, Davies teaches an inhalation device wherein each medicament retainer comprises a cavity in the elongate carrier.

40. **As to claim 35**, Davies teaches an inhalation device wherein each medicament retainer has a seal **404**, the device additionally comprising an actuator **416,470,471** for unsealing a medicament retainer at the access position.

41. **As to claim 36**, Davies teaches an inhalation device wherein the seal comprises a sealing tape **404** arranged along the elongate carrier and wherein each successive cavity is accessible by peelable removal of the tape from the elongate carrier.

42. **As to claim 37**, Davies teaches an inhalation device wherein an end of the sealing tape connects to the actuator and peelable removal of the sealing tape is achievable by movement of the actuator relative to the elongate carrier (**See Pages 18-19**).

43. **As to claim 38**, Davies teaches an inhalation device wherein the mover is rotatable relative to the housing such that rotation of the mover results in coiling of the tape around the actuator (**See Pages 18-19**).

44. **As to claim 39**, Davies teaches an inhalation device wherein the mover is an axially mounted tapered pole and the actuator is also an axially mounted tapered pole

(See Pages 18-19; See Figure 16 which shows actuator 470 to be tapered from bottom to top).

45. **As to claim 41**, Davies teaches an inhalation device comprising a housing **410** having an air inlet **140,121**, an air outlet, and an airway therebetween; an elongate carrier **401** having a plurality of doses thereon, wherein the elongate carrier is storable in a flat spiral configuration; and a mover **472,473,475** in communication with the elongate carrier for helically extending the elongate carrier such as to serially move each dose to an access position.

46. **As to claim 42**, Davies teaches an inhalation device wherein the air outlet is provided with a mouthpiece **420**.

47. **As to claim 43**, Davies teaches the use of an inhalation device for the administration of medicament to a patient.

48. Claims 26 and 40 are rejected under 35 U.S.C. 102(b) as being anticipated by Everett (EP 0469814).

49. **As to claim 26**, Everett teaches an inhalation device comprising a housing **12** having an air inlet **23**, an air outlet **22** and an airway therebetween; a substantially planar **(the Examiner considers the carrier to be substantially planar and having a first face when viewing the carrier from the side)** medicament carrier **39** having a plurality of medicament retainers **41** in a single spiral path arrangement in the plane of the medicament carrier, each medicament retainer having a seal **See Col.3, line 33**; an actuator **See Col. 3, lines 46-56** for progressively unsealing each medicament retainer on the spiral path. **Please note that Davies teaches a single spiral path as much as**

Applicant teaches a single spiral path given that applicant has not defined in the specification what a single spiral path constitutes.

50. As to claim 40, Everett teaches an inhalation device wherein the actuator comprises a piercer 31 for piercably unsealing a medicament retainer. The Examiner considers the plunger/hammer of Everett to be a piercer since it ruptures the retainer as does a piercer.

Double Patenting

51. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

52. Claims 1, 3, 4, 5, 6, 7, 8, 9, 15, 21, 22, 23, 24, 26, 27, 28, 29, 30, 31, 32, and 40 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-2, 3, 4, 7, 8, 9, 11, 12, 14, 17-18, 19, 20, 21, 29, 31, 32, 33, 34, 35, and 36 respectively of U.S. Patent No. 6,679,254. Although the conflicting claims are not identical, they are not patentably distinct from each other because the patented claims 1-2 have additional features not found in claim 1 of the

instant application; claim 21 of the instant application includes additional features not found in the patented claims 17-18; and claim 26 of the instant application omits features not found in claim 29 of the patent.

53. Claim 1 of the instant application teaches all the limitations of the patented claims 1-2 but omits "wherein each concentric circular path is independently rotatable relative to and is lockably engageable to an adjacent ring thereto" Furthermore, claim 1 of the instant application recites the additional feature of "single" spiral path arrangement. However, it would have been obvious to one of ordinary skill in the art that a concentric circular path is one that is a single spiral path arrangement with a common point of origin.

54. Claim 3 of the instant application has limitations which are found in claim 3 of the patent.

55. Claim 4 of the instant application has limitations which are found in claim 4 of the patent.

56. Claim 5 of the instant application has limitations which are found in claim 7 of the patent.

57. Claim 6 of the instant application has limitations which are found in claim 8 of the patent.

58. Claim 7 of the instant application has limitations which are found in claim 9 of the patent.

59. Claim 8 of the instant application has limitations which are found in claim 11 of the patent.

60. Claim 9 of the instant application has limitations which are found in claim 12 of the patent.

61. Claim 15 of the instant application has limitations which are found in claim 14 of the patent.

62. Claim 21 of the instant application teaches all the limitations of the patented claims 17-18 but recites the additional feature of "single" spiral path arrangement.

However, it would have been obvious to one of ordinary skill in the art that a concentric circular path is one that is a single spiral path arrangement with a common point of origin. Claim 21 also recites the additional feature of "on a planar face of said carrier." However, it would have been obvious to one of ordinary skill in the art that the retainers lie on some plane of the carrier.

63. Claim 22 of the instant application has limitations which are found in claim 19 of the patent.

64. Claim 23 of the instant application has limitations which are found in claim 20 of the patent.

65. Claim 24 of the instant application has limitations which are found in claim 21 of the patent.

66. Claim 26 of the instant application teaches all the limitations of the patented claims 29 but omits "a mover for moving the medicament carrier relative to the housing so as to bring successive medicament retainers individually into communication with the airway" Furthermore, claim 1 of the instant application recites the additional feature of "a substantially planar" and "single" spiral path arrangement "in the plane of the

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medicament carrier". However, it would have been obvious to one of ordinary skill in the art that a concentric circular path is one that is a single spiral path arrangement with a common point of origin and it resides on some plane on the carrier.

67. Claim 27 of the instant application has limitations which are found in claim 26 of the patent.

68. Claim 28 of the instant application has limitations which are found in claim 31 of the patent.

69. Claim 29 of the instant application has limitations which are found in claim 32 of the patent.

70. Claim 30 of the instant application has limitations which are found in claim 33 of the patent.

71. Claim 31 of the instant application has limitations which are found in claim 34 of the patent.

72. Claim 32 of the instant application has limitations which are found in claim 35 of the patent.

73. Claim 40 of the instant application has limitations which are found in claim 36 of the patent.

Conclusion

74. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

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§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mital B. Patel whose telephone number is 703-306-5444. The examiner can normally be reached on Monday-Friday (8:00 - 4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry Bennett can be reached on 703-308-0101. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Mital B. Patel
Examiner
Art Unit 3743

mbp

Henry Bennett
Supervisory Patent Examiner
Group 3700